

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

GEORGE S. SCHAFFER, Individually and
on Behalf of All Others Similarly Situated,

Plaintiff(s),

vs.

HORIZON PHARMA PLC, TIMOTHY P.
WALBERT, PAUL W. HOELSCHER,
JOHN J. KODY, ROBERT F. CAREY,
WILLIAM F. DANIEL, MICHAEL GREY,
JEFF HIMAWAN, VIRINDER NOHRIA,
RONALD PAULI, GINO SANTINI,
H. THOMAS WATKINS, CITIGROUP
GLOBAL MARKETS, INC., JEFFERIES
LLC, COWEN & COMPANY LLC, AND
MORGAN STANLEY & CO. LLC,

Defendants.

Master File No.: 1:16-cv-01763-JMF

JURY TRIAL DEMANDED

ORAL ARGUMENT REQUESTED

**UNDERWRITER DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' CLAIMS
UNDER SECTION 11 AND SECTION 12 OF THE SECURITIES ACT**

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Defendants Citigroup Global Markets, Inc., Jefferies LLC, Cowen & Company LLC, and Morgan Stanley & Co. LLC (collectively, the “Underwriter Defendants” or “Underwriters”) respectfully submit this memorandum of law in support of their motion to dismiss Plaintiffs’ claims under Section 11 and Section 12 of the Securities Act asserted in the Amended Consolidated Complaint filed on October 7, 2016 (the “Amended Complaint”).

PRELIMINARY STATEMENT

In April 2015, Horizon Pharma plc, a publicly traded specialty biopharmaceutical company that develops and markets medicines for arthritis pain and inflammation, effected a secondary offering of common stock. The Offering Prospectus included a detailed description of the company’s business model and marketing strategy, along with 58 pages of disclosures that painstakingly laid out the risks to its business. Horizon continued to be successful in the months following the Offering, but in the second half of 2015, buffeted by adverse news articles highlighting information that Horizon had already disclosed to shareholders, as well as by the materialization of some of the very risks to which prospective investors had been alerted, Horizon’s stock price declined.

The Amended Complaint asserts claims under Sections 11 and 12(a)(2) of the Securities Act against Horizon, its Board of Directors, and the Underwriters of the Offering. Plaintiffs do not allege that any statement made in the Offering Prospectus was false and do not claim that Horizon guaranteed that its business model would continue to be successful. Instead, the Amended Complaint alleges that Horizon’s prospectus failed to predict that the risks of which it warned would actually materialize post-offering and failed to characterize the company’s business model in the pejorative terms Plaintiffs prefer. These omission claims are flatly inconsistent with the disclosures Horizon did make—which fully and accurately describe all

material aspects of, and the risks associated with, Horizon's business model, its pricing plans and strategies, its sales and marketing efforts, and its relationships with pharmacies. Those disclosed risks later materialized, when Horizon's fully disclosed strategy of selling drugs at huge price multiples over readily available substitute products faced wide-spread condemnation, which caused investors losses.

Plaintiffs also assert that Horizon omitted to provide certain granular information about some of its alleged business practices, as well as details about certain activities of the designated mail order pharmacies with which Horizon did business. But these business practices, which take up so much space in the Amended Complaint, are not alleged to have become public or to have been the cause of a drop in Horizon's stock price. These incidental details about some of the marketing tactics of Horizon and the designated pharmacies are immaterial as a matter of law. They have nothing to do with the risks of Horizon's pricing strategy or the reasons it ultimately proved unsuccessful in the marketplace. Horizon had no duty to disclose those details. Plaintiffs are complaining of investment losses that came about as the result of the materialization of *disclosed* risks that investors knew about when they chose to buy Horizon shares.

FACTUAL BACKGROUND

Horizon is a publicly traded specialty biopharmaceutical company engaged in identifying, developing, acquiring or licensing and commercializing medicines for the treatment of arthritis pain, inflammation, and rare diseases in the United States and internationally.

In April 2015, Horizon conducted a secondary offering of 17,652,500 shares of common stock at \$28.25 per share (the "Offering"). In connection with the Offering, Horizon published a Registration Statement and Prospectus, a Preliminary Prospectus Supplement, and a Final

Prospectus Supplement (collectively, the “Offering Documents”). The Underwriter Defendants acted as underwriters for the Offering. The Offering Documents included a detailed description of Horizon’s business model and marketing strategy, along with 58 pages of disclosures that painstakingly laid out the risks to its business. The Offering Documents also incorporated prior public filings by Horizon, which also apprised investors of the company’s operations, its strategies and the attendant risks.

The Amended Complaint

The Amended Complaint asserts two distinct categories of claims, on behalf of two separate classes of investors. First, the Amended Complaint asserts securities fraud claims against Horizon and four of its officers under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. The first 299 paragraphs of the Amended Complaint exclusively concern Plaintiffs’ Exchange Act claims, which involve disclosures by Horizon during the period January 2015 to April 2016. These claims are *not* asserted against the Underwriter Defendants.

The Amended Complaint also contains claims against Horizon, its directors (the “Horizon Defendants”), and the Underwriters under Sections 11 and 12(a)(2) of the Securities Act of 1933. For their Securities Act claims, Plaintiffs seek to represent a class of persons limited to those who purchased Horizon stock “pursuant and/or traceable” to the offering materials issued in connection with Horizon’s Offering. The allegations in support of Plaintiffs’ Securities Act claims are exclusively contained in paragraphs 300–429 of the Amended Complaint. This section has a separate heading—“THE SECURITIES ACT CLAIMS” (Amended Complaint p. 116)—which begins by alleging jurisdictional grounds and identifying the parties relevant to Plaintiffs’ Securities Act claims. (¶¶ 305–324.) In effect, Plaintiffs filed two separate complaints that have been stapled together.

The Amended Complaint does not allege that any information in Horizon’s financial statements was inaccurate. The Securities Act claims in the Amended Complaint focus on four categories of purported omissions from the Offering Documents, and one category of affirmative forward-looking statements. Specifically, Plaintiffs claim that:

1. Horizon failed to disclose that it “was operating an unsustainable business model” (§ 412) and “would be forced to slash prices on its biggest growth drivers” (§ 410);
2. Horizon failed to disclose that it “engaged in illegal sales and marketing tactics” (§ 410);
3. Horizon failed to disclose that it “exercised secret operational control” over pharmacies in its patient assistance program (§ 335);
4. Horizon failed to disclose that Horizon and the pharmacies that participated in the patient assistance program “relied on improper, dishonest, and illegal conduct in violation of various laws, regulations,” and certain contractual terms (§ 355); and
5. Three forward-looking statements expressing optimism about Horizon’s patient assistance program were false and misleading (§§ 378, 380).

Although the Securities Act claims are more narrowly focused than the fraud claims, and solely concern the Offering Documents, each of the five foregoing categories of factual allegations is also featured (often verbatim) in the longer portion of the Amended Complaint devoted to the fraud claims. Accordingly, the Underwriter Defendants incorporate by reference the discussion of these claims reflected in the brief submitted by the Horizon Defendants.

Horizon’s Business Strategy And Disclosed Risks

In 2011, Horizon brought to market DUEXIS, a fixed-dose combination of a pain reliever medication and a gastrointestinal protection medication in a single pill.¹ In 2013, Horizon acquired rights to market VIMOVO, a drug with active ingredients similar to those in DUEXIS. Horizon repeatedly disclosed to investors that both of these flagship products—which together

¹ Ex. A (Prospectus Supplement) S-4. All exhibit references are to the accompanying Declaration of Richard A. Rosen dated November 14, 2016. All “§” references are to the Amended Complaint.

accounted for approximately 83% of Horizon’s net sales in 2014—were not protected by patents and were vulnerable to competition from lower priced generics.² Horizon also disclosed that it intended to increase the prices of VIMOVO and other drugs to bring them in line with the higher prices charged for DUEXIS, to increase the value Horizon would receive per prescription.³

Horizon also disclosed in its Offering Documents that it administers a “Prescriptions-Made-Easy” (“PME”) patient assistance program. Horizon explained that the PME program, which originated in 2012, was “a key part of our commercial strategy” and was designed to help Horizon continue to gain market share in the face of increasing “pressure from healthcare payors and pharmacy benefit managers” on physicians and patients “to use less expensive generic or over the counter brands” instead of Horizon’s drugs. (Ex. B p. 41; *see also* Ex. A S-5.)

As the Offering Documents described, through the PME program Horizon seeks to reduce eligible patients’ out-of-pocket costs for prescriptions by designating a small number of mail order pharmacies to fill prescriptions for Horizon’s drugs. These designated pharmacies ship Horizon’s drugs directly to patients. Horizon subsidizes the cost of the drugs in the event that an insurer refuses to cover the prescription.⁴

Horizon highlighted the differences between these designated pharmacies and “traditional pharmacies”:

Through PME, prescriptions for our products are filled by designated mail order specialty pharmacies, with the products shipped directly to the patient. Because our products when dispensed through the PME program do not require involvement of a traditional retail pharmacy, prescriptions filled through our PME program are less likely to be subject to the efforts of traditional pharmacies to

² See Ex. B (10-K for 2014) p. 96.

³ See Ex. A S-25.

⁴ See Ex. A S-5; Ex. B p. 41.

switch a physician's intended prescription of our products to a generic or over the counter brand.⁵

The PME program thus helps patients receive the prescription drugs they need without interference or delay on the part of insurers or pharmacies. Horizon encourages physicians to invite their patients to fill prescriptions, including prescriptions for DUEXIS or VIMOVO, through the PME program. Horizon fully disclosed these mechanics of the PME program to investors, and Horizon emphasized that the PME program was a key to its future success.⁶

The Offering Documents also underscored the salient risks associated with Horizon's business model. The first page of the Prospectus warned potential investors, in large, bold font: **"Investing in our ordinary shares involves risks. See "Risk Factors" beginning on page S-18."** (Ex. A S-1.) The Prospectus instructs prospective investors to read the 58-page "Risk Factors" section "before making an investment decision." (Ex. A S-4.)⁷

Horizon warned that if it was unable to execute the PME program successfully, it *"may not be able to generate significant product revenues or execute on [Horizon's] business plan."* (Ex. A S-23.) Horizon disclosed that the success of the PME program relied on "physician and patient awareness and comfort with the program," while acknowledging that Horizon had limited ability to influence physicians and patients to utilize the PME program. (Ex. A S-24.)

Horizon highlighted the risk that price increases could be met with negative reactions from consumers, governmental regulators and insurance companies, and that the materialization of such risks would adversely affect the success of its business.⁸ Horizon explicitly alerted

⁵ Ex. A S-5; *see also* Ex. B p. 41.

⁶ *See* Ex. A S-5, S-24.

⁷ The salient risk factors and descriptions of Horizon's business strategy are included in the list of disclosures attached as Appendix A to this brief.

⁸ *See* Ex. A S-47; Ex. B pp. 35, 42.

investors to the fact that these risks had actually *already* materialized to some extent, with consequences adversely impacting Horizon’s business. Specifically, the Offering Documents disclosed that in July 2014 Express Scripts and CVS Caremark, two Pharmacy Benefit Management (“PBM”) companies—third-party administrators of health plans that make coverage recommendations to health benefit providers—had placed DUEXIS and VIMOVO on their lists of excluded drugs, effective January 2015. (Ex. A S-24.) Horizon further disclosed that these PBMs had accounted for approximately 20% to 30% of prescriptions for DUEXIS and VIMOVO and warned that other PBMs could place DUEXIS and VIMOVO on their exclusions lists as well. (*Id.*; Ex. B p. 41.) In the Amended Complaint, Plaintiffs acknowledge that Horizon disclosed these risks and that the market was aware of their potential consequences.⁹

Horizon’s strategy of marketing DUEXIS and VIMOVO through the PME program was successful both before and after the Offering. The company saw a positive trend in sales of DUEXIS in the months prior to the Offering, with sales in the first quarter of 2015 exceeding \$28.8 million—a 107 percent increase from the prior year.¹⁰ Horizon’s stock price rose from \$2.01 per share in 2013 to \$38.45 per share in July 2015. In the second and third quarters of 2015, DUEXIS sales climbed to \$44.2 million and \$56.9 million, respectively, representing year-over-year growth of 148 and 150 percent.¹¹ Horizon’s stock price increased from \$28.25 per share in April 2015 to \$38.45 per share in July 2015.

Horizon’s stock price declined later in 2015, however, due to a number of market factors, including adverse publicity and decisions by additional PBMs to place DUEXIS and VIMOVO on their exclusion lists. The Amended Complaint itself makes clear that it was wide-spread

⁹ See ¶¶ 9, 53, 54; *see also infra* pp. 10–13.

¹⁰ See Ex. C (May 2015 10-Q) p. 29.

¹¹ See Ex. D (August 2015 10-Q) p. 32; Ex. E (November 2015 10-Q) p. 38.

information about the huge disparity between the prices charged by Horizon and the prices at which equivalent drugs could readily be obtained that caused Horizon's sales to drop. Thus, the Amended Complaint says "the truth [began] to emerge" in October 2015 when the New York Times published an article highlighting the cost of Horizon's products. (¶ 114.) The article said:

Drug Makers Sidestep Barriers on Pricing

The Pain reliever Duexis is a combination of two old drugs, the generic equivalents of Motrin and Pepcid.

If prescribed separately, the two drugs together would cost no more than \$20 or \$40 a month. By contrast, Duexis, which contains both in a single pill, costs about \$1,500 a month.

Needless to say, many insurers do not want to pay for Duexis. Yet sales of the drug are growing rapidly, in large part because its manufacturer, Horizon Pharma, has figured out a way to circumvent efforts of insurers and pharmacists to switch patients to the generic compounds, or even to the over-the-counter versions.

It is called "Prescriptions Made Easy."

* * *

"What was started as administering complex, costly drugs has been co-opted as a sales/marketing tool to drive the growth of minor differentiation standard retail drugs," Ronny Gal, a pharmaceutical analyst at Bernstein, said in a note on Friday.¹²

In sharp contrast, the Amended Complaint does not (and could not) assert that disclosures about the sales practices of Horizon or the PME pharmacies caused doctors to stop prescribing its products, or caused more PBMs to place those products on their exclusion lists. In short, the risks of which Horizon had specifically warned in the Offering Documents actually materialized, with a detrimental impact on Horizon's share price.

¹² ¶ 114. Similarly, Plaintiffs also rely in the Amended Complaint on a November 10, 2016 New York Times article that described Horizon's "use of mail-order dispensaries to help *lift sales of expensive drugs*." (¶ 123 (emphasis added).) And the October 2015 press release by Depomed, Inc. quoted in the Amended Complaint also focused on Horizon's "aggressive drug pricing practices". (¶ 119.)

ARGUMENT

I. PLAINTIFFS FAIL TO STATE A CLAIM UNDER SECTION 11 OR SECTION 12 OF THE SECURITIES ACT.

Plaintiffs fail to state a claim under Section 11 or Section 12(a)(2) of the Securities Act because the Amended Complaint does not sufficiently allege that the Offering Documents either contained an “untrue statement of a material fact” or “omitted to state a material fact . . . necessary to make the statements therein not misleading.” 15 U.S.C. §§ 77k(a), 77l(a)(2).

Courts routinely dismiss Securities Act claims based on alleged omissions when the offering documents sufficiently warned investors of the relevant facts and risks. *See In re ProShares Trust Sec. Litig.*, 889 F. Supp. 2d 644, 653 (S.D.N.Y. 2012), *aff’d*, 728 F.3d 96 (2d Cir. 2013) (granting motion to dismiss Securities Act claims where the registration statements at issue “stated in plain English . . . the precise risk that the plaintiffs allege later materialized”).¹³ Horizon had no duty to go beyond the detailed description of its pricing strategy and its use of designated mail order pharmacies and disclose immaterial and granular details of its interactions with individual physicians to promote its products, or all of the sales practices of the pharmacies. *See Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988) (holding that the materiality standard should not be set “too low” due to the real risk that “a minimal standard might bring an

¹³ *See also In re TVIX Secs. Litig.*, 25 F. Supp. 3d 444, 453 (S.D.N.Y. 2014) (finding that alleged omissions cannot support a Securities Act claim where the offering documents disclosed the fundamental risks); *Scott v. Gen. Motors Co.*, 46 F. Supp. 3d 387 (S.D.N.Y. 2014), *aff’d*, 605 F. App’x 52 (2d Cir. 2015) (dismissing Securities Act claims against underwriter defendants after finding that plaintiffs failed properly to allege a material misstatement or omission in offering documents); *In re Morgan Stanley Tech. Fund Sec. Litig.*, 643 F. Supp. 2d 366 (S.D.N.Y. 2009), *aff’d*, 592 F.3d 347 (2d Cir. 2010) (same).

overabundance of information within its reach, and lead management simply to bury the shareholders in an avalanche of trivial information”).¹⁴

A. Plaintiffs Fail to Identify Any Actionable Misstatement in the Offering Documents, or Any Material Omission that Horizon Had a Duty to Disclose.

1. Plaintiffs’ contention that Horizon failed to disclose in the Offering Documents that Horizon “was operating an unsustainable business model” and “would be forced to slash prices on its biggest growth drivers” is specious.

Plaintiffs allege that, in the Offering Documents, Horizon “did not disclose . . . the fact that Horizon was operating an unsustainable business model” (¶ 412; *see id.* ¶ 373) and “failed to disclose the Company would be forced to slash prices on its biggest growth drivers” (¶ 410). This claim is without merit.

First, the Amended Complaint does not allege that any affirmative statement in the Offering Documents about Horizon’s business model or its pricing strategy was false. Nor does the Amended Complaint allege that Horizon ever guaranteed or predicted that the prices or sales volumes of its products would remain the same or would increase. Plaintiffs cannot claim that Horizon’s truthful statements describing its business model and pricing strategy were misleading simply because Horizon failed to predict that, months after the Offering, its prices would be reduced or its business model would come under attack. *See Szulik v. Tagliaferri*, 966 F. Supp. 2d 339, 362 (S.D.N.Y. 2013) (in order to survive a motion to dismiss under a theory of actionable omission, plaintiff must “specify a statement that is alleged to be materially misleading because of the information it omits”).

¹⁴ *See also Ganino v. Citizens Utilities Co.*, 228 F. 3d 154, 162 (2d Cir. 2000) (ruling an alleged omission can only be found to be material if “a reasonable investor would have considered [the alleged omission] significant in making investment decisions”); *Rudman v. CHC Group Ltd.*, 2016 WL 6583788 at *7 (S.D.N.Y. Nov. 7, 2016) (“[C]ompanies must choose to what granular level they will disclose [required information] . . . [Defendant corporation] had no duty to provide a level of detail satisfactory to plaintiffs, only to make sure that once it spoke on a matter, it did so fairly and accurately.”).

Second, the Amended Complaint does not allege facts indicating that, at the time of the Offering, Horizon knew or believed that its business model was “unsustainable” or that the company would be forced to slash prices. Horizon had no duty to predict this adverse future development or to assume the worst, and there is no obligation that a company disparage itself or describe its position in a pejorative manner.¹⁵

Third, the risks of Horizon’s business model and the potential impediments to its success were disclosed fully and accurately in the Offering Documents. As noted above, Horizon had disclosed in its 10-K for 2014, which was incorporated by reference into the Offering Documents, that DUEXIS and VIMOVO accounted for approximately 83% of the company’s net sales in 2014. (*See* Ex. B p. 96.) In the Offering Documents, Horizon disclosed that DUEXIS and VIMOVO were at risk of competition from generic drug manufacturers and marketers, noting that physicians and pharmacies often have incentives to prescribe lower-cost generics as opposed to prescribing DUEXIS and VIMOVO through the PME program. The Offering Documents explained: “If we are unsuccessful in convincing physicians to complete prescriptions through our PME program or otherwise provide prescribing instructions prohibiting the substitution of [generic drugs] as [] substitut[es] for DUEXIS or . . . VIMOVO . . . , sales of DUEXIS, [] and VIMOVO may suffer” (Ex. A S-33–S-34; *see also* Ex. B pp. 26, 50.)

The Offering Documents also described Horizon’s strategy to increase the price of VIMOVO and disclosed the risks associated with the planned price increases:

¹⁵ *See In re Ultrafem Inc. Sec. Litig.*, 91 F. Supp. 2d 678, 699 (S.D.N.Y. 2000) (“A company has no duty to disparage its own competitive position.”); *Singh v. Schikan*, 106 F. Supp. 3d 439, 449 (S.D.N.Y. 2015) (“In the absence of data establishing that [a clinical trial of the company’s pharmaceutical product] would not meet its endpoints, defendants were not required to predict negative results or to hypothesize its failure.”); *see also Washtenaw Cnty. Emps.’ Ret. Sys. v. Princeton Rev., Inc.*, 2012 WL 727125, at *8 (D. Mass. Mar. 6, 2012) (“[T]here is no requirement that [defendant] pejoratively characterize its endeavors in the bleakest possible terms in order to make its disclosures complete and not misleading.”).

Following our acquisition of the U.S. rights to VIMOVO in November 2013 . . . , our strategy has included bringing [VIMOVO's] pricing in-line with DUEXIS, thereby significantly increasing the value we realize per prescription, and also increasing sales and marketing support to drive growth in prescriptions. We cannot guarantee that this strategy will continue to be effective generally, due to negative reactions to price increases or otherwise. (Ex. A S-25.)

Horizon cautioned in the Offering Documents that payors and health care providers might reject Horizon's flagship products in favor of lower-cost generics: "There may be additional pressure by payors and healthcare providers to use generic drugs that contain the active ingredients found in DUEXIS . . . and VIMOVO" (Ex. A S-48.) Horizon explained that if healthcare providers rejected its drugs in favor of generics, it "would have a material adverse effect on our business, results of operations, financial condition and prospects." (*Id.*)

Horizon disclosed in the Offering Documents that its success depended upon the inclusion of DUEXIS and VIMOVO in major PBMs' formularies. Horizon noted that "we may experience a significant decline in DUEXIS and VIMOVO prescriptions as a result of formulary exclusions."¹⁶ Horizon also warned in the Risk Factors that PBMs may take "adverse actions against us, which could materially adversely affect our operating results."¹⁷

Horizon twice highlighted in the Offering Documents that two significant PBMs had already placed DUEXIS and VIMOVO on their exclusion lists, and emphasized the risk that additional PBMs might place DUEXIS and VIMOVO on their exclusion lists as well:

[T]wo of the largest PBMs, which we estimate to currently control approximately 20% to 30% of prescriptions for DUEXIS and VIMOVO, placed DUEXIS and VIMOVO on their exclusion lists beginning in 2015. Additional healthcare plans, including those that contract with these PBMs but use different formularies, may also choose to exclude our products from their formularies or restrict coverage to situations where a generic or over-the-counter product has been tried first. (Ex. A S-24, S-48; *see also* Ex. B pp. 3, 41.)

¹⁶ Ex. A S-24, S-48; *see also* Ex. B pp. 3, 41.

¹⁷ Ex. A S-47; *see also* Ex. B p. 60.

Indeed, in the Amended Complaint, Plaintiffs acknowledge that Horizon disclosed these risks in the Offering Documents, and that the market was well aware of the potential impact to Horizon’s business model: “Horizon disclosed that it had been notified that two of the largest PBMs, CVS Caremark [] and Express Scripts had decided to place DUEXIS and VIMOVO on their exclusion lists. Horizon disclosed that an estimated 20%-30% of DUEXIS and VIMOVO prescriptions could be impacted immediately. Horizon and *its investors understood that that number could quickly grow.*” (§ 9 (emphasis added).) Plaintiffs also acknowledge that investors were aware that “there was also the danger of a bigger impact” (§ 53) if more PBMs placed DUEXIS and VIMOVO on their exclusion lists: “*The market understood that being added to the excluded list could spell disaster.*” (§ 54 (emphasis added).)

Horizon also disclosed in the Offering Documents that it relied on a small number of pharmacies to implement the PME program, and that the success of the PME program could be adversely impacted if there were negative developments involving those pharmacies:

[W]e depend on a limited number of PME pharmacies to fulfill patient prescriptions under the PME program The commercialization of our products and our operating results could be affected should any of the PME pharmacies choose not to continue participation in our PME program or by any adverse events at any of those PME pharmacies. (Ex. A S-24; *see also* Ex. B p. 42.)

Plaintiffs cannot now complain that the materialization of those risks—which Plaintiffs acknowledge Horizon disclosed and of which Plaintiffs admit the market was aware—entitles them to relief under the Securities Act.

2. Plaintiffs’ allegations that Horizon failed to disclose in the Offering Documents that it was engaged in “illegal sales and marketing tactics” are without merit.

Plaintiffs allege that the Offering Documents “failed to disclose that . . . in order to meet PME program sales objectives, Horizon engaged in illegal sales and marketing tactics.” (§410.)

First, Plaintiffs do not allege that any affirmative statement Horizon made about Horizon’s PME program was false.

Second, the seven paragraphs of the Amended Complaint addressing Securities Act claims about Horizon’s own sales and marketing do not even *allege* illegality. The Amended Complaint alleges only that certain Horizon practices violated its internal code of conduct. (¶ 366.) Thus, any claim based on “non-disclosure” of an illegal scheme must be dismissed. *See In re Axis Capital Holdings, Ltd., Sec. Litig.*, 456 F. Supp. 2d 576, 585 (S.D.N.Y. 2006).

In any event, the sales and marketing practices at issue (which are described in both the fraud and Securities Act sections of the Amended Complaint in almost identical wording), are neither misleading nor improper, as discussed more fully in Horizon Defendants’ Brief (at pp. 13–17). These include:

- incentivizing sales representatives to establish close relationships with doctors (¶¶ 367–68);
- emphasizing “the benefits of the [PME] program” and the fact (not alleged to be false) that patients would be subject to a minimal co-pay rather than discussing the prices of drugs (¶ 369); and
- marketing Horizon drugs to orthopedic surgeons who might prescribe them for off label but permissible uses (such as acute post-surgical pain) (¶¶ 370–71).

Significantly, moreover, the Amended Complaint fails to allege that any of these alleged sales practices have ever been found by any court or regulator to have been illegal or improper.

Plaintiffs’ advocacy and pejorative characterizations are not “facts”.

More fundamentally, these details about exactly *how* Horizon’s sales representatives interacted with doctors, and the specifics of its sales pitches, are simply immaterial as a matter of law.¹⁸ Horizon had no duty to go into this level of detail about its marketing initiatives. Just

¹⁸ *See Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988) (“[T]here must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable

because Plaintiffs’ counsel found a single confidential witness who shared his generalized impressions about some of the ways in which Horizon’s sales force purportedly interacted with doctors, it by no means follows that information about these practices would have been material to investors. What investors needed to know—and unquestionably did know—was that Horizon was making a huge bet that, using the designated pharmacy structure, it could persuade physicians and patients to use its high-priced products instead of low cost generic substitutes. Horizon’s stock price declined when this marketing strategy failed to deliver the sales investors hoped for—which is entirely unrelated to the propriety of the sales practices that the confidential witnesses describe.

3. Plaintiffs fail to state a claim that “Horizon exercised secret operational control” over the pharmacies in the PME program.

Plaintiffs allege that, in the Offering Documents, Horizon failed to disclose that “Horizon relied on a small group of pharmacies over which it exercised secret operational control to distribute the Company’s drugs through the PME program.” (¶ 335.) This claim is meritless.

First, Plaintiffs do not allege that any affirmative statement Horizon made in the Offering Documents about its relationships with the PME participating pharmacies was false.

Second, Plaintiffs fail adequately to allege that Horizon in fact controlled any PME pharmacy. The Horizon Defendants’ Brief shows that the Amended Complaint’s fraud allegations are devoid of particularized facts to support the pejorative “captive” label; that showing is equally applicable to the (virtually identical) Securities Act allegations on this subject. As explained more fully in the Horizon Defendants’ Brief (pp. 21-23), Plaintiffs do not

investor as having significantly altered the ‘total mix’ of information made available.”); *Resnik v. Swartz*, 303 F. 3d 147, 154 (2d Cir. 2002) (“[T]he securities laws must impose a duty to disclose the omitted information. Disclosure of an item of information is not required, however, simply because it may be relevant or of interest to a reasonable investor.”).

allege that Horizon owned any PME participating pharmacy or had an option to purchase any PME participating pharmacy. Horizon did, however, make clear that, although independent of Horizon, there were only “a limited number” (Ex. A S-24) of “designated mail order specialty pharmacies” (*id.* S-5) that Horizon differentiated from “traditional retail pharmac[ies]” (*id.*), which were crucial for the success of Horizon’s business model and the operation of its PME program. For any kind of program like this to work, any reasonable investor would expect collaboration and exchange of information between Horizon and these pharmacies. It is thus entirely unsurprising that Horizon would communicate with the PME participating pharmacies (¶ 336); visit the PME participating pharmacies’ facilities (¶ 346); and meet with PME participating pharmacies’ executives (¶ 337).

In any event, for the reasons discussed above, the details of Horizon’s daily interactions with the designated pharmacies is simply immaterial, and Horizon had no duty to convey all of these operational details to investors. They have no bearing on the risk of the investment that ultimately came to pass.

4. Plaintiffs fail to state a claim that “Horizon and its controlled pharmacies relied on improper, dishonest, and illegal conduct in violation of various laws, regulations, and PBM contractual terms.”

Plaintiffs allege that Horizon did not disclose that “Horizon and its controlled pharmacies relied on improper, dishonest, and illegal conduct in violation of various laws, regulations, and PBM contractual terms.” (¶ 355.) This claim is meritless.

First, Plaintiffs do not allege that any affirmative statement Horizon made about its conduct or the conduct of the pharmacies designated to fill prescriptions through the PME program was false.

Second, the handful of paragraphs that allege Horizon “relied on” illegal conduct by pharmacies does not assert that Horizon itself did anything illegal. Instead, the claim appears to

be that certain pharmacies involved in the PME program engaged in illegal conduct (§§ 356–359), and that these practices purportedly violated Horizon’s internal code of conduct (§ 366).

Plaintiffs describe the allegedly “improper, dishonest, and illegal conduct” purportedly omitted from the Offering Documents in paragraphs 356–365 of the Amended Complaint. These ten paragraphs, which are essentially recycled verbatim from the fraud allegations, focus on the conduct of PME participating pharmacies—not on Horizon’s conduct. As set forth in more detail in the Horizon Defendants’ Brief (pp. 13-17), Plaintiffs’ allegations regarding the pharmacies’ “improper” behavior are insufficient.

Moreover, the Amended Complaint fails to allege that any of these alleged sales practices have ever been found by any court or regulator to have been improper. The Amended Complaint’s reliance on a New York Times article describing Horizon’s PME program as a *legal* practice is no substitute for factual allegations that the challenged conduct was illegal. (§ 353.) In the two instances that Plaintiffs actually allege that PME participating pharmacies engaged in conduct that was “illegal” (§§ 356–357, 358–359), Plaintiffs do not specify any conduct *by Horizon* that Plaintiffs claim to have been illegal. *See* Horizon Defs.’ Brief at pp.11-17.

Plaintiffs have failed to allege facts indicating that Horizon had a duty to disclose any inappropriate activities by pharmacies that it did not own and over which it did not exercise control. These allegations accordingly fail to state a claim under the Securities Act. *See In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 402–404 (S.D.N.Y. 2016) (holding that a corporation does not have a duty to disclose allegedly improper conduct of which it has no knowledge).¹⁹

Moreover, as with the allegations derived from confidential witnesses concerning Horizon’s own sales practices, these putative “facts” are in any event immaterial as a matter of

¹⁹ *See also In re Citigroup, Inc. Sec. Litig.* 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) (“[F]ederal securities laws do not require a company to accuse itself of wrongdoing.”).

law. Even if adequately pleaded (which they are not), these details about some of the behavior of some of the pharmacies in the PME network have nothing to do with the risks an investor needed to know before deciding to buy Horizon shares—witness the fact that it was the failure of the pricing strategy, not revelations about alleged misconduct by retail pharmacies, that caused Horizon’s sales to decline and its stock price to drop. The possibility that the pricing strategy might fail is a risk about which investors were warned.

B. Plaintiffs’ claims based on forward-looking statements about the PME program protected by the safe harbor of the PSLRA should be dismissed.

The only affirmative statements in the Offering Documents of which Plaintiffs complain (all of which concern the PME program) are protected by the safe harbor of the Private Securities Litigation Reform Act of 1995 (the “PSLRA”). 15 U.S.C. § 77z-2(c)(1)(A)–(B).

Plaintiffs focus on three statements expressing optimism about the PME program:

- “In December 2014, we began execution of a comprehensive plan creating a new organization focused on the acceleration of our PME program to ensure continued growth of our NSAID portfolio in 2015”;
- “We believe the continued expansion of our PME program will allow us to largely mitigate the potential impact of our products being placed on the exclusion lists implemented by PBMs”; and
- “We expect that continued adoption of our PME program by physicians will be important to our ability to gain market share for our products.”

(¶ 378; Ex. B pp. 3, 23.) But these are *all* classic examples of forward-looking statements protected by the safe harbor of the PSLRA. *See SRM Global Fund Ltd. P’ship v. Countrywide Fin. Corp.*, 448 F. App’x 116, 118 (2d Cir. 2011) (“[O]ptimistic statements about future profitability constitute non-actionable forward-looking statements.”).

A defendant cannot be held liable for a forward-looking statement if “the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading.” *Golesorkhi v.*

Green Mountain Coffee Roasters, Inc., 569 F. App'x 43, 44 (2d Cir. 2014). Plaintiffs allege no facts in the Amended Complaint showing that the Horizon Defendants had *actual knowledge* that their very generalized statements of optimism about the utility of the PME program were false or misleading at the time they were made. Accordingly, none of the forward-looking statements made by the Horizon Defendants can support a Securities Act claim.²⁰

Indeed, the Court need not look any further than the Amended Complaint itself to determine that Plaintiffs have failed to allege actual knowledge of falsity with respect to their claims under the Securities Act. The Amended Complaint states:

Plaintiffs expressly disclaim any allegations of fraud or intentional misconduct in connection with these non-fraud claims . . . except that any challenged statements of opinion or belief made in connection with the Offering are alleged to have been materially misstated statements of opinion or belief when made at the time of the Offering. (¶ 304.)

In their Securities Act claims, “Plaintiffs exclude allegations that could be construed as alleging fraud or intentional misconduct, as this Count is based solely on claims of strict liability and/or negligence.” (¶ 399.) Plaintiffs cannot have it both ways. By excluding all allegations of scienter from their Securities Act claims, Plaintiffs have pled themselves out of court with respect to forward-looking statements because they “disclaim[ed] any allegation sounding in fraud or deception.” *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015). Judge Swain reached the same result under the Securities Act with respect to statements of opinion because the plaintiffs “disavowed any allegation that the

²⁰ Plaintiffs include a single allegation that “Defendants are liable for those false and misleading forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false and misleading, and/or the forward-looking statement was authorized and/or approved by an executive officer of Horizon who knew that those statements were false and misleading when made.” (¶ 398.) This conclusory allegation is insufficient to render the safe harbor inapplicable. *See Slayton v. Am. Exp. Co.*, 604 F.3d 758, 773 (2d Cir. 2010) (holding the safe harbor requires dismissal if plaintiffs do not “state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter”).

[d]efendants knowingly misstated any opinions” in their offering documents. *In re Am. Intern. Grp., Inc., 2008 Sec. Litig.*, 2013 WL 1787567, at *5–6 (S.D.N.Y. Apr. 26, 2014).

Moreover, each forward-looking statement was accompanied by voluminous meaningful risk disclosures (described above at pp. 11–13) and therefore is protected by the safe harbor for this independent reason as well. *In re Alliance Pharm. Corp. Sec. Litig.*, 279 F. Supp. 2d 171, 192 (S.D.N.Y. 2003) (“[W]hen a prospectus—read as a whole—bespeaks caution of the very risk that plaintiffs complain was not disclosed, a plaintiff cannot successfully claim that the forward-looking statement was misleading.”); 15 U.S.C. § 77z-2(c)(1)(B).

C. Items 303 and 503 of Regulation S-K do not create an independent duty for Horizon to disclose the allegedly omitted information regarding the foregoing subjects.

Invoking Items 303 and 503 of Regulation S-K, Plaintiffs allege—in a section of only four paragraphs—that Horizon failed to disclose required information in the Offering Documents and in the documents incorporated by reference. (¶¶ 409–412.) Plaintiffs fail, however, to allege that Regulation S-K required Horizon to make the disclosures Plaintiffs seek.

1. Plaintiffs fail to allege that any defendant had actual knowledge of an omitted trend, uncertainty or event—a necessary element for their Item 303 claims.

Item 303 requires registrants to disclose “known trends or uncertainties” that the company expects to materially impact sales, revenues, or income. *See* 17 C.F.R. § 229.303(a)(3)(ii); *Ind. Pub. Ret. Sys. v. SAIC, Inc.*, 818 F.3d 85, 95 (2d Cir. 2016). Plaintiffs fail to identify either (1) any adverse economic event that occurred prior to the Offering that was not fully disclosed in the Offering Documents, or (2) any negative financial trend of which Horizon was aware before the Offering that it did not adequately disclose. Instead, Plaintiffs merely recycle the defective allegations that Horizon failed to disclose that it “exercised control over a number of its PME specialty partner pharmacies” and “engaged in illegal sales and marketing

tactics”—which are not allegations about economic “events” or “trends”. (¶ 410; *see also* ¶¶ 343, 376(b).)

As to the claims that Horizon should have predicted that it “would be forced to slash prices on its biggest growth drivers,” and “that payor pushback would impact Horizon’s primary care drugs, primarily DUEXUS and VIMOVO” (¶ 410), no such negative event or trend existed at the time of the Offering for Horizon to disclose, and Plaintiffs identify none. In fact, as discussed above at p. 7, Horizon was enjoying a *positive* trend, as sales of DUEXIS were increasing in the period before and immediately after the Offering. As a result, Plaintiffs cannot allege that Horizon, in the period prior to the Offering, was suffering a discernible trend or pattern of undisclosed losses or erosion of its business. In fact, the entire theory of the Amended Complaint is that Horizon’s business was not adversely affected until *after* the public disclosure of its relationship with PME participating pharmacies, and *after* the public disclosure of the accusation concerning employment of illegal marketing practices, and so on—none of which is even *alleged* to have occurred until October 2015, which is when the Amended Complaint contends that “the truth begins to emerge”. (¶ 113.)

Plaintiffs’ Item 303 claims are further undermined by their inability to allege that any defendant had knowledge of any adverse “trends” prior to or as of the time of the Offering. While “Section 11 claims generally do not require pleading scienter, Item 303’s requirement of knowledge requires that [a Section 11 plaintiff relying on Item 303] plead, with some specificity, facts establishing that the defendant had actual knowledge of the purported trend.” *Blackmoss Invs. Inc. v. ACA Capital Holdings, Inc.*, 2010 WL 148617, at *9 (S.D.N.Y. Jan. 14, 2010).²¹

²¹ *See also Garber v. Legg Mason, Inc.*, 537 F. Supp. 2d 597, 614 (S.D.N.Y. 2008) (holding that merely “pleading a trend’s *existence*” fails to satisfy Item 303’s requirement that “the trend actually be *known*”); *In re IAC/InterActive Corp Sec. Litig.*, 695 F. Supp. 2d 109, 118

Judge Sweet’s opinion in *Blackmoss* is instructive on this point. The plaintiff in that case alleged that the defendant company, an insurer and manager of collateralized debt obligations, violated Item 303 and Section 11 by failing to disclose, in connection with its IPO, a “rising trend of delinquencies and foreclosure in sub-prime [residential mortgage backed securities].” 2010 WL 148617, at *9–10. The plaintiff primarily relied, however, upon news articles and financial data on the housing market “published after the IPO,” which accordingly could not “be used to establish knowledge of a trend prior to the IPO.” *Id.* To the extent that the plaintiff pointed to any data prior to the IPO, that data established, at most, “increased foreclosure rates over the prior two months.” *Id.* Judge Sweet held that “[a]s a matter of law, a two month period of time does not establish a ‘trend’ for purposes of the disclosures required by Item 303.” *Id.*

Here, there is even less evidence of a “trend” than existed in *Blackmoss*. It is undisputed that sales of DUEXIS were rising, not falling, before the Offering. Plaintiffs’ Item 303 claims rest exclusively on market developments that occurred long *after* the common stock offering was issued. Such after-the-fact developments “cannot be used to establish knowledge . . . prior to the [offering].” *Id.*²² Even if “it may be possible to say that seeds of what was to come were available to defendants,” in an Item 303 case “we cannot attribute to defendants, based on hindsight alone, knowledge that events that may well have appeared unremarkable at the time, were omens of future material problems.” *Medina v. Tremor Video Inc.*, 640 F. App’x 45, 49

(S.D.N.Y. 2010) (“Defendants’ actual knowledge of the trend is an essential allegation for purposes of a claim based on Item 303.”).

²² See also *In re Lions Gate Entm’t Corp. Sec. Litig.*, 2016 WL 297722, at *15 (S.D.N.Y. Jan. 22, 2016); *In re Francesca’s Holdings Corp. Sec. Litig.*, 2015 WL 1600464, at *18 (S.D.N.Y. Mar. 31, 2015) (dismissing plaintiff’s claim that Item 303(a) of Regulation S-K required disclosure of defendant’s “deteriorating” vendor relationships because plaintiff did not allege that defendant had knowledge of the allegedly deteriorating relationship).

(2d Cir. 2016). Moreover, Plaintiffs have gone out of their way to disavow any assertion, in connection with their Securities Act claims, that Defendants acted with knowledge or intent.²³

2. Plaintiffs fail to state a claim under Item 503 of Regulation S-K.

Item 503 requires that certain filings “provide under the caption ‘Risk Factors’ a discussion of the most significant factors that make the offering speculative or risky.” *In re Lions Gate*, 2016 WL 297722, at *15 (citing 17 C.F.R. § 229.503(c)). Plaintiffs’ contention that the Offering Documents should have disclosed that Horizon “was operating an unsustainable business model” under Item 503 is without merit. “Although there is scant caselaw on Item 503,” the inquiry can be boiled down to “whether the Offering Documents were accurate and sufficiently candid.” *Christine Asia Co., Ltd. v. Alibana Grp. Holding Ltd.*, 2016 WL 3648965, at *17 (S.D.N.Y. June 24, 2016). Despite Plaintiffs’ conclusory assertions, it is inarguable that Horizon’s SEC filings amply disclosed all material aspects of the PME program and the commercial, regulatory, and reputational risks associated with it. (*See supra* pp. 10–13.) Moreover, as reflected in detail in the Horizon Defendants’ Brief (pp. 6, 28), Plaintiffs’ characterization of the PME program as “unsustainable” is an exercise in 20/20 hindsight that is belied by the undisputed numbers: net sales for DUEXIS for 2015 exceeded those in 2014.

II. PLAINTIFFS LACK STANDING TO ASSERT CLAIMS UNDER SECTION 12 OF THE SECURITIES ACT.

Plaintiffs’ Section 12(a)(2) claims should be dismissed for the independent reason that the Amended Complaint fails to allege that the named plaintiffs pursuing the claims purchased any common stock at all at the time of, or that can be traced to, the Offering. The Amended Complaint therefore does not adequately allege that any of the named plaintiffs has statutory standing to bring a Section 12(a)(2) claim.

²³ *See* pp. 19–20, *supra*.

The Amended Complaint alleges that Lead Plaintiff Northern California Carpenters “purchased *or otherwise acquired* Horizon common stock issued in the Offering” (¶ 414 (emphasis added)) and that these purchases were made “*pursuant and traceable* to the Company’s Registration Statement” (¶ 33 (emphasis added)). These allegations are strikingly similar to allegations courts have found insufficient to establish Section 12 standing.

“Standing under Section 12(a)(2) is more restrictive than under Section 11,” and requires that a plaintiff show that he or she directly purchased securities from a defendant in a public offering. *Boilermakers Nat. Annuity Tr. Fund v. WaMu Mortg. Pass Through Certificates, Series ARI*, 748 F. Supp. 2d 1246, 1253 (W.D. Wash. 2010).²⁴ Courts regularly dismiss Section 12 claims for insufficiently detailing how and when the plaintiffs purchased the securities in question.²⁵ And courts repeatedly have made clear that a vague assertion that a named plaintiff purchased securities “pursuant and/or traceable” to offering documents, as alleged by Plaintiffs here, is “insufficient to assert standing for Section 12 claims.” *New Jersey Carpenters Health Fund v. DLJ Mortgage Capital, Inc.*, 2010 WL 1473288, at *4 (S.D.N.Y. Mar. 29, 2010).²⁶

²⁴ See also *In re Petrobras Sec. Litig.*, 2015 WL 4557364, at *13 (S.D.N.Y. July 30, 2015) (“[S]tanding to assert a Section 12(a)(2) claim is limited to persons who directly purchase securities from the defendant in a public offering, rather than on the secondary market.”) (citing *Gustafson v. Alloyd Co., Inc.*, 513 U.S. 561, 578 (1995)).

²⁵ See *Plumbers’ Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 658 F. Supp. 2d 299, 305 (D. Mass. 2009), *aff’d in part, vacated in part*, 632 F. 3d 762 (1st Cir. 2011) (“[Plaintiffs must] squarely allege that the securities at issue were purchased in a public offering If plaintiffs did in fact purchase the Certificates directly from the defendants, they should have said so. An evasive circumlocution does not suffice as a substitute.”); *In re Sterling Foster & Co., Sec. Litig.*, 222 F. Supp. 2d 216, 245 (E.D.N.Y. 2002) (dismissing Section 12(a)(2) claim for failure to state explicitly whether purchases were made in the offering or in the secondary market).

²⁶ See also *Pub. Emps.’ Ret. Sys. of Miss. v. Merrill Lynch & Co. Inc.*, 714 F. Supp. 2d 475, 484 (S.D.N.Y. 2010) (finding allegation that plaintiffs “purchased or otherwise acquired” securities “pursuant and/or traceable” to offering documents insufficient for standing purposes); *In re Cosi, Inc. Sec. Litig.*, 379 F. Supp. 2d 580, 589 (S.D.N.Y. 2005) (rejecting plaintiffs’ argument that “the allegation that they bought their shares ‘pursuant to or traceable

Before the Offering, Horizon already had slightly under 130 million shares available to the public. The 15,350,000 shares in the Offering represent 10.57% of the total outstanding shares after the Offering. It is thus highly unlikely that Lead Plaintiff's shares were purchased in the Offering. Accordingly, Plaintiffs' Section 12 claims should be dismissed on the basis that Plaintiffs do not adequately allege in the Amended Complaint that the Lead Plaintiff purchased shares directly from one of the defendants in the Offering and not on the secondary market.

CONCLUSION

For the foregoing reasons, this Court should grant this motion and dismiss Plaintiffs' Amended Complaint against the Underwriter Defendants with prejudice.

Dated: November 14, 2016

Respectfully submitted,

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to' the Prospectus is sufficient to state a claim under § 12(a)(2)"); *In re UBS AG Sec. Litig.*, 2012 WL 4471265, at *27 (S.D.N.Y. Sept. 28, 2012) (dismissing Section 12(a)(2) claim for failing to offer any "degree of detail" beyond simply alleging the purchase of the securities "in connection with, and traceable to" an offering).